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| 10/827,106 | 04/19/2004 | Gopi M. Venkatesh | EUR-A-008/00US 307853-2228 | 1448 |
| 58349 7590 04/16/2009 COOLEY GODWARD KRONISH LLP ATTN: Patent Group Suite 1100 777 - 6th Street, NW WASHINGTON, DC 20001 | | | | |
| EXAMINER | | | | |
| SAMALA, JAGADESHWAR RAO | | | | |
| ART UNIT | | PAPER NUMBER | | |
| 1618 | | | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary**Application No.**

10/827,106

Applicant(s)

VENKATESH ET AL.

Examiner

JAGADISHWAR R. SAMALA

Art Unit

1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 January 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SG/US)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Election Restriction

Applicant's election with traverse of group I, claims 1-15 in the reply filed on 01/26/2009 is acknowledged. The traversal is on the ground(s) that examining a tablet that rapidly disintegrates in the oral cavity comprising various steps and a method for manufacturing a tablet that disintegrates in the oral cavity comprising steps does not present the examiner with a search burden. This is not found persuasive because claims 1-15 and 16-24 differ in scope as indicated by their distinct modes of preparation, for example claims 16-24, active ingredient having an average particle diameter of not more than about 50 microns and compressing includes pre-lubricating the dies and punches prior to tablet compression. As such claims 16-24 are withdrawn from further consideration pursuant to 37 CFR 1.142 (b), as being drawn to nonelected claims. The requirement is still deemed proper and is therefore made **FINAL**.

Claim Rejections - 35 USC § 103

1. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

2. Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gowan (US 5,876,759) in view of Ohta Motohiro et al (EP 914818 A1) and Guo et al (US 2004/0068000 A1).

Applicant's claims are drawn to a tablet that rapidly disintegrates in the oral cavity comprising a compressed blend of: rapidly dispersing microgranules of sugar alcohol, and taste-masked microcapsules containing at least one drug and at least one polymeric binder, wet milling the granulated mass, and microencapsulating the milled granules to provide microcapsules.

Gowan discloses a rapidly disintegrating pharmaceutical dosage form (tablet) containing coated pharmaceutical particles with a taste-masking composition comprising a water-disintegratable, carbohydrate, and a binder and a process for preparing such dosage forms (col. 2 lines 27-32). Pharmaceutical actives include famotidine, ranitidine, cimetidine mixtures thereof (col. 6 lines 28-37), water-disintegratable carbohydrates include mannitol, sorbitol, dextrose, sucrose, xylitol, lactose, and mixtures thereof (col. 3 lines 23-25); binders include cellulosic derivatives, polyvinyl pyrrolidone, starch, modified starch (col. 3 lines 32-36). The coated particle refers to solid pharmaceutical actives in the form of a crystal or particle, an agglomerate of individual particles or a granulated particle which would read on microencapsulating the microgranules to provide microcapsules. The coated pharmaceutical particles have particle size generally less than 400 microns and disintegrates in the mouth within about 30 seconds (col. 7 lines 32-34). Additional disclosure includes dosage forms upon

administration, coated pharmaceutical particles are released from the dosage form with no objectionable taste and swallowed by the user (col. 3 lines 5-8).

Gowan does not teach separately granulating a sugar alcohol or a saccharide or a mixture thereof having an average particle size less than about 30 micron to provide rapidly dispersing microgranules and drug sumatripan.

Ohta discloses a method of preparing a rapidly disintegrating tablet comprising sugar alcohol or saccharide having an average particle diameter of not more than 30 microns, an active ingredient, and a disintegrant (see 0004). The tablet can be obtained by compressing and tableting after granulating a mixed powdered component comprising sugar alcohol such as D-mannitol or saccharide ground by means of a hammer mill or a jet mill or the like (see 0018). The disintegrant mainly used such as croscopovindone, crosscarmellose sodium, low substituted hydroxypropylcellulose or the like which is widely used for drugs and food (see 0016). The amount of sugar alcohol or saccharide is preferably about 60-95 % by weight of tablet (see 0006 and 0019). The amount of active ingredient fore e.g. cimetidine is 0.01-10 %, and the amount of disintegrant present is preferably about 1-30mg per dosage, and more preferably 1- 10 % per one tablet (see 0021).

Guo discloses a pharmaceutical composition of a compression coated tablet comprising a tablet core containing an effective amount of a bitter or unpleasant tasting pharmaceutically active agent such as sumatripan and a compression coat on the tablet core (abstract and 0023). And core composition comprise a disintegrant, croscopovindone (0009), binders include starch, polyvinylpyrrolidone or hydroxypropylmethylcellulose

(0012), fillers like lactose, sorbitol, mannitol and the like (0010). Additional disclosure includes that the oral dosage form, sumatriptan's unpleasant taste and smell may exacerbate the nausea and vomiting associated with migraine is reduced by formulating dosage form as a tablet, which is compression coated by non-interacting materials thereby eliminating the bitter taste and unpleasant smell of the active pharmaceutical ingredient (0004).

It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate sugar alcohol or saccharide, such as D-mannitol or lactose having an average particle diameter of not more than 30 microns into the tablets as taught by Gowan to reduce the undesirable taste or bitterness of the pharmaceutical and providing with a pleasant taste perception. The person of ordinary skill in the art would have been motivated to make these modification, because Gowan teaches, that coated pharmaceutical particles with a taste-masking composition comprising a water-disintegratable carbohydrate, and a binder upon administration are released from the dosage form with no objectionable taste and swallowed by the user, and reasonably would have expected success because both Gowan and Ohta teaches a rapidly disintegrating tablet that can be used in the same field of endeavor such as taste-masking tablets, which could improve the patient's compliance and acceptance with the drug regime.

Response to Arguments

Applicant argues that Ohta describes tablets comprising a single type of drug-containing granule, i.e., prepared by granulating together a sugar alcohol or saccharide,

a drug (not taste-masked), and a disintegrant and lacking a polymeric binder. This argument is not persuasive since Ohta reference is combined for its teaching of knowledge in the art of taste-masked tablets (cimetidine), wherein D-mannitol is used to reduce the undesirable taste or bitterness of the pharmaceutical and providing with a pleasant taste of the tablets and Guo reference to a pharmaceutical composition comprising compression coated taste masked solid dosage forms of sumatriptan and pharmaceutically acceptable carriers or excipients such as starch, hydroxypropyl cellulose, polyvinylpyrrolidone or hydroxypropylmethylcellulose as binders (0006 and 0012)..

Conclusion

1. No claims are allowed at this time.
2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAGADISHWAR R. SAMALA whose telephone number is (571)272-9927. The examiner can normally be reached on 8.30 A.M to 5.00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571)272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jake M. Vu/
Examiner, Art Unit 1618

Jagadishwar R Samala
Examiner
Art Unit 1618

sjr